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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,988	07/15/2002	Jurgen Markl	GKS-102.0(7911/86349)	2621
24628	7590	03/21/2005	EXAMINER	
WELSH & KATZ, LTD 120 S RIVERSIDE PLAZA 22ND FLOOR CHICAGO, IL 60606			MAYER, SUZANNE MARIE	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

*Office Action Summary*

Application No.

10/049,988

Applicant(s)

MARKL ET AL.

Examiner

Suzanne M. Mayer, Ph.D.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-35 and 38-42 is/are pending in the application.
- 4a) Of the above claim(s) 26-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-25, 32-35 and 38-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Applicants' election with partial traverse of Group VIII, claims 25-35 and 38-42 drawn to SEQ ID No: 75 in the reply filed on 17 February 2005 is acknowledged. The traversal is on the grounds that domains b through h should not be severable and restricted from the entire protein, and should be joined with SEQ ID No: 75 which is drawn to domain c from *Megathura crenulata*. It is further submitted that the sequences from the different organism, *Haliotis tuberculata* should also be joined and searched together with those from *M. crenulata* because the proteins are orthologs that share high homology and thus a search of one would overlap with another. This is not found persuasive because each domain from both proteins possesses different immunological functions and thus are patentably distinct from one another because each can be used in a different capacity from one another or even the entire protein as a whole even. Furthermore, Applicants argument that hemocyanin domains b-h, and as an example of this SEQ ID Nos: 42-48, represents the entire protein and thus should be examined together, however, this clearly is not the case since SEQ ID Nos:42,43,46 and 48 are only partial domains. Thus these sequences do make up the entire KLH2 protein. Furthermore, just because proteins from different organisms share sequence homologies does not mean that they are not patentably distinct inventions because they may have different structures and/or functions. Furthermore, the search for each protein sequence claimed would a separate search by the Examiner which would

constitute an undue search burden because of the amount of time needed to review the large amount of data expected to be obtained by the search.

The requirement is still deemed proper and is therefore made FINAL.

### ***Status of the Claims***

2. Upon reconsideration, the Examiner will include claim 24 in the elected Group VIII and thus Claims 24-35 and 38-42, drawn to SEQ ID No: 75 which is domain c from *Megathura crenulata* KLH2 hemocyanin, are pending in this application. However, claims 26-31 are drawn to non-elected subject matter as they are drawn to other sequences other than the elected SEQ ID No: 75 and are therefore withdrawn from further consideration. Additionally, non-elected claims 1-23, 36-37 and 43-50 are also withdrawn from consideration. Claims 24-25, 32-35 and 38-42 are thus pending.

### ***Priority***

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Information Disclosure Statement***

4. The information disclosure statement (IDS) submitted on 15 July 2003 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner. Foreign Patent EP-0 252 829 A1 has

not been considered by the Examiner as no English translation of the document or abstract was provided. See signed and attached PTOL-1449.

### ***Specification***

5. The abstract of the disclosure is objected to because it too long. Applicant is reminded that the length of the Abstract should not exceed 150 words. Correction is required. See MPEP § 608.01(b).
6. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

### **Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or  
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

Art Unit: 1653

- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Specifically what is missing in the specification of the instant application is (b) (this should be stated in the first line of the specification), (e), (f), (g) and (h).

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 101***

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 24 and 25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Polypeptide sequences encoding a structural protein exists in nature. The claimed invention does not show the "hand of man." Amending the claim to require that the polypeptide is isolated would be remedial.

### ***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1653

10. Claims 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Gebauer et al. (1994 - Cited on the IDS submitted on 15 July 2003). Gebauer et al. teach the isolation and separation of individual subunits from KLH2 and their molecular masses as assessed by SDS-PAGE. Specifically, Figure 4L shows the isolation of the c subunit of KLH2 derived from *M. crenulata*. The claims are anticipated because, by all comparable data, the invention now claimed and the protein of the prior art are the same or equivalent protein because the genus and species of bacteria are identical, the relative molecular weight of the protein isolated in the gel is identical. In addition, the protein has the same or equivalent amino acid sequence whether the amino acid sequence is known or not, as the amino acid sequence is an inherent characteristic of a protein or polypeptide.

11. Claims 38-42 are rejected under 35 U.S.C. 102(b) as being anticipated by the 1995 Sigma Product Catalog. An acceptable pharmaceutical composition of KLH from *M. crenulata* is taught on p. 520, product number H 7017, of the 1995 Sigma catalog. Since the instant claims read on a pharmaceutical composition *comprising* a hemocyanin polypeptide, the claims read on full length KLH which comprise all of the KLH hemocyanin polypeptides. The intended use language in claims 39-42 do not carry any patentable weight since the composition ultimately remains the same.

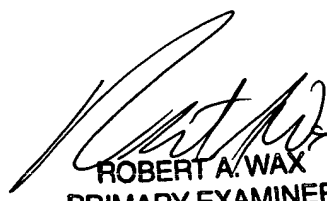
**Conclusion**

12. No claim is allowed.
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Mayer, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 8.30am to 5.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Smm*  
SMM  
11 March 2005

  
ROBERT A. WAX  
PRIMARY EXAMINER  
Art Unit 1653